



Attorney's Docket No. 2475-010559

APPEAL BRIEF TRANSMITTAL LETTER

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents
P. O. Box 1450
Alexandria VA 22313-1450

	VA 22313-1450					
Serial No.:	rial No.: 10/008,292			Filing Date: November 13, 2001		
Examiner:				Group Art Ur	nit: <u>1661</u>	
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Theresa Ulinski

10/14/2003

Date

Application No. 10/008,292 Appeal Brief Dated October 14, 2003 Confirmation No. 2712

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OCT 1 7 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

10/008,292

Applicant

Jan Man

Filed

November 13, 2001

Title

BEGONIA PLANT NAMED

'NADINE'

Group Art Unit

1661

Examiner

Kent L. Bell

APPEAL BRIEF

MAIL STOP APPEAL BRIEF – PATENTS Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Appeal Brief is submitted in support of the Notice of Appeal filed on August 14, 2003 appealing the final rejection of claim 1.

The headings used hereinafter and the subject matter set forth under each heading are in accordance with 37 C.F.R. § 1.192(c).

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on October 14, 2003.

Theresa Ulinski
(Name of Person Mailing Paper)
Signature
Date

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Ι

REAL PARTY IN INTEREST

Begonia Breeders Associates B.V. is the Assignee of the entire right, title, and interest to the above-identified application and, as such, is the real party in interest in this Appeal.

II

RELATED APPEALS AND INTERFERENCES

Other Appeals known to the Appellant, the Appellant's legal representative, or the Assignee of the present application which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal include Appeals filed in the following applications assigned to the Assignee of the present application: 10/012,139; 10/010,496 and 10/007,711. Appellant's legal representative is handling other such Appeals for other Applicants/Assignees and is also aware of other Appeals handled by other legal representatives directed to the same issue.

There are no interferences known to the Appellant, the Appellant's legal representative, or the Assignee of the above-identified application which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

Ш

STATUS OF CLAIMS

Claim 1 is finally rejected under 35 U.S.C. § 102(b) for anticipation by Plant Breeder's Rights Application No. BGN0268 (The Netherlands) in view of a sale of a plant named 'Nadine' in The Netherlands on November 1, 1999;

Claim 1 is reproduced in Appendix A which is attached hereto.

IV

STATUS OF AMENDMENTS

No response after the final Office Action dated May 14, 2003 has been submitted in this case. There was no claim change made after the final Office Action. The claim on appeal is the claim as filed with the application on November 13, 2001 which refers to the specification and drawing, the specification having been amended by the Amendments of August 5, 2002 and February 20, 2003.

 \mathbf{V}

SUMMARY OF THE INVENTION

The claim on appeal in the present application is directed to a variety of begonia named 'Nadine' which is described in detail on four pages of the specification and illustrated in a photograph. The claimed variety is a selection from a population of seedlings resulting from a mutation of its parent cultivar and possesses all of the botanical characteristics fully described and shown in the present application.

VI

ISSUE PRESENTED

The following issue is presented in this Appeal:

Is claim 1 anticipated by a foreign Plant Breeder's Rights (PBR) Application in view of a sale of a variety of begonia named 'Nadine' outside of the United States in 1999?

VII

GROUPING OF CLAIMS

There is a single claim in the application, claim 1, and no grouping is applicable.

VIII

ARGUMENTS

I. An anticipation rejection cannot be built from multiple references.

The sale of a variety of begonia named 'Nadine' outside the United States only indicates that a begonia plant was in the possession of the public one year prior to the patent application filing date. To the extent that the sold variety was the same as the claimed variety, such a sale outside the United States is not a statutory bar under 35 U.S.C. § 102(b) which prohibits patenting of an invention which "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country".

Combining the sale of a claimed variety outside the United States with the scant disclosure in a PBR application constitutes improper use of prior art under 35 U.S.C. § 102(b) to build an "anticipation" rejection. It is well-settled that teachings of multiple references may not be combined to build an anticipation rejection. <u>Studiengesellschaft Kohle, M.B.H. v. Dart Industries, Inc.</u>, 726 F.2d 724, 727, 220 USPQ 841, 842 (Fed. Cir. 1984).

The anticipation rejection in the present application has been characterized as based on the cited PBR document. According to the Examiner, the cited PBR document teaches every material element of the claim, despite its severe lack (or absence) of botanical information. The sale of a plant named 'Nadine' outside the United States supposedly is used to show that the plant disclosed in the PBR document was in the public domain more than one year prior to the application filing date.

The rejection is flawed in its reliance on a publication which does not disclose every material element of the claim and its attempt to circumvent 35 U.S.C. § 102(b) to reject a claim on an invention that may have been sold outside the United States.

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The Office Action of November 20, 2002 recognizes that a publication which is relied upon as prior art under 35 U.S.C. § 102(b) must be enabling. Moreover, it is admitted at page 6 of that Office Action that a PBR application "by itself would not be an enabled publication, were the plant not in the public domain". To account for the deficient teachings of a PBR application, namely, the inability of a PBR application to enable the claimed plant, the rejection is supplemented by possible prior public availability of the claimed plant. The November 20, 2002 Office Action asserts that In re Samour, 571 F.2d 559, 197 USPQ1 (CCPA 1978) and In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) support this rejection. Application of that case law to the present case is inappropriate.

The following comments set forth the proper standards for using multiple references in a § 102(b) rejection, namely, how an additional printed publication (a true § 102(b) reference) may be used to show that anticipatory prior art is in the public domain.

Use of multiple references to make a rejection under 35 U.S.C. § 102(b) II.

It is well-established that a printed publication which discloses "every material element of the claimed subject matter" constitutes a bar under 35 U.S.C. § 102(b) if more than one year prior to an application's filing date, it placed the claimed subject matter "in possession of the public". In re Samour, 571 F.2d at 562, 197 USPQ at 3. See also, In re Donohue, 766 F.2d at 533, 226 USPQ at 621 ("It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it".)

Anticipation rejections based on multiple references require a Α. primary enabling disclosure and a second written reference.

There is some flexibility in the rule that only one reference may be used in an anticipation rejection. An additional reference may be used to prove that the primary reference discloses subject matter which is in the public's possession. MPEP § 2131.01. Pursuant to this exception, a secondary reference may be included in an anticipation rejection only when the primary reference in and of itself is an enabling disclosure. An additional

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reference may be used to show what the primary reference contains -- and not to supplement what the primary reference lacks. In both of <u>In re Samour</u> and <u>In re Donohue</u> (each relating to patent applications on chemical inventions), an additional written reference was relied upon to show that the subject matter of a primary reference was available to the public. Neither case stands for the proposition that an additional reference may be used to supplement a non-enabling disclosure of a primary reference.

The claim at issue in <u>In re Samour</u> was directed to a specific chemical compound with the structure appearing in the claim. A first prior art reference disclosed the structural formula set forth in the claim, but the reference did not disclose a method for its preparation. Hence, the applicant argued that the first reference was non-enabling. In response, the Examiner cited an additional reference which disclosed a method for preparing similar types of compounds. On appeal from a final rejection, the Patent and Trademark Office Board of Appeals agreed that the additional reference provided a legally sufficient teaching of how to make the compound disclosed in the first reference. The court agreed that the mere recitation of the chemical formula of the claimed composition in a prior art reference would not have been sufficient to place the compound in the public's possession. Yet, the court was willing to consider relying on additional references:

... [s]olely as evidence that, more than one year prior to appellant's filing date, a method of preparing the claimed subject matter (DMMP) would have been known by, or would have been obvious to, one of ordinary skill in the art. Therefore, the key issue before us is whether the PTO, in making a rejection under 35 USC § 102(b) on a single prior art reference that discloses every material element of the claimed subject matter, can properly rely on additional references for such purpose.

Id. at 562, 197 USPQ at 4 (emphasis added).

The court maintained the rejection of the claim for the chemical compound based on the combined teachings of the printed publication disclosing the compound and a reference which disclosed a method for making similar compounds explaining that the additional reference cited in the § 102(b) rejection was "not relied on for a suggestion or incentive to combine teachings to meet the claimed limitations" (as in a rejection under 35

U.S.C. § 103), but, rather, to show that the claimed subject matter, every material element of which is disclosed in the primary reference, was in the possession of the public. <u>Id.</u> at 563, 197 USPQ at 4.

The <u>Samour</u> court did not import any disclosure from the secondary reference into the disclosure of the primary reference which taught every material element of the claimed compound. Every material element of the claim was the structural formula of the claimed compound. The primary reference disclosed that same structural formula. The secondary reference was only used to demonstrate that the claimed subject matter, which was fully disclosed in a printed publication, was available to the public.

A similar reasoning and result was found in <u>In re Donohue</u> where a claim also directed to a set of chemical compounds was rejected for anticipation by a primary reference that did not disclose methods of preparing the claimed compounds. Additional references relied upon by the United States Patent and Trademark Office taught how such compounds could be produced. The legal basis for upholding the rejection was outlined as follows:

It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. *In re Sasse*, 629 F.2d 675, 681, 207 USPQ 107, 111 (CCPA 1980); *In re Samour*, 571 F.2d at 562, 197 USPQ at 4; *see also Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 64, 651-52, 223 USPQ 1168, 1173 (Fed. Cir. 1984). Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. *See In re LeGrice*, 301 F.2d at 939, 133 USPQ at 373-74. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling. *In re Borst*, 345 F.2d 851, 855, 45 USPQ 554, 557 (CCPA 1965), *cert. denied*, 382 U.S. 973, 148 USPQ 771 (1966).

Id. at 533, 226 USPQ at 621 (footnote deleted).

The court specifically followed the rule of <u>Samour</u> to determine that the claimed subject matter was in the public's possession by looking to additional references.

The additional references utilized in this case (viz., Lincoln and Wagner) are not relief [sic] upon for suggestion or motivation to combine teachings to meet the claim limitations, as in rejections under 35 U.S.C. § 103. *In re Samour*, 571 F.2d at 563, 197 USPQ at 4-5. Such reliance would be pointless because Nomura [the primary reference] discloses every element claimed. The purpose of citing Lincoln and Wagner is, instead, to show that the claimed subject matter, as disclose [sic] in Nomura, was in the public's possession.

Id.

Both <u>In re Samour</u> and <u>In re Donohue</u> involved claims to a class of chemical compounds that was fully disclosed in a prior art reference. The secondary references (printed publications) in both cases were not employed to supplement any need for additional disclosure not present in the primary reference so that one skilled in the art could comprehend the scope of that referenced disclosure but only to show that the claimed chemical compounds were within the public domain. In other words, on their faces, the primary references were "enabling" because they taught every material element of the claimed subject matter. The only reliance on a secondary reference was to show that the claimed subject matter was in the public's possession one year prior to the filing date of the patent applications for the chemical compounds.

This line of case law was recently followed in <u>Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. et al.</u>, 246 F.3d 1368, 58 USPQ2d 1508 (Fed. Cir. 2001). Ben Venue and its codefendants alleged invalidity of a patent obtained by Bristol-Myers for a method of treating a cancer patient having steps of (i) premedicating the patient with a first drug and (ii) administering a second drug. The defendants argued that Bristol's claim was anticipated by a prior art reference which not only described treating patients with the second drug (i.e., the second step) but also suggested that "[f]urther studies are needed to see if *pretreatment regimens* [i.e., the first step], ... will permit the safe administration of this compound". <u>Id.</u> at 1372, 58 USPQ2d at 1515-1516. At issue was whether the prior art reference which mentioned a pretreatment regimen was "enabling to one of skill in the art" one year before the filing date of Bristol's patent application based on additional references

and teachings to pretreat cancer patients. Following both <u>Samour</u> and <u>Donohue</u>, the court noted that enablement of an anticipatory reference may be demonstrated by another reference (as in <u>Samour</u> and <u>Donohue</u>, a printed publication) and restated the requirement of "a showing of each limitation of a claim in a single reference" for anticipation. <u>Id</u>. The court concluded that it was proper to look at other references to establish that the pretreatment regimen mentioned in the primary reference was in the public domain one year prior to Bristol's filing date. As was true for the claims at issue in <u>Donohue</u> and <u>Samour</u>, every material element of the claim in <u>Bristol-Myers</u> was present in the primary reference, namely, (i) premedicating a patient with a first drug and (ii) administering to the patient a second drug. The primary reference contained both of those limitations and additional printed publications were only relied upon to show that premedicating a patient was within the public domain one year prior to the filing date of the patent application. No subject matter from the secondary reference was used to supplement the disclosure of the primary reference.

Hence, there are two requirements for using an additional reference to "enable" a primary reference in forming an anticipation rejection.

- 1. The primary reference must contain "every material element of the claimed invention"; and
- 2. The additional reference (a printed publication) is relied upon only to demonstrate that the claimed subject matter was in the possession of the public one year prior to the filing date of the patent application.
- B. Sale of patentable subject matter outside of the United States is not a prior art "reference" and cannot be used to enable another reference under 35 U.S.C. § 102(b).

It is elementary chemistry to realize that the disclosure of a compound's formula is enough to anticipate the claimed chemical formula because that formula is indeed the entire invention. The <u>Samour</u> and <u>Donohue</u> courts agreed that a secondary piece of prior art (a written publication) could be used to show the state of the art in the chemical field was

in the public's possession. However, disclosure of the botanical name (and possibly a few other particulars) of a new and unanticipated asexually reproduced plant variety is not enough to anticipate a plant patent for the claimed variety.

In the present application, the Examiner relies on <u>Samour</u> and <u>Donohue</u> to support a position that the sale of a variety named 'Nadine' in The Netherlands is some type of "reference" that indicates what knowledge was in the public domain. However, this line of cases permits use of a true reference, an additional piece of prior art (a pre-application filing date publication), as evidence of the knowledge in the public domain. The sale of an invention outside the United States is not such a reference.

It is contrary to longstanding tenets of the patent laws to assert that sale of a claimed invention outside of the United States qualifies as a reference at all. The sale of a variety named 'Nadine' outside the United States is not prior art. It is not a reference which is appropriate to use as evidence of the public's knowledge. An assertion that the sale of a claimed invention outside the United States as a reference (per Samour and Donohue) would vitiate the meaning of the on-sale bar of 35 U.S.C. § 102(b).

If the Examiner's position is maintained, it would be changing the landscape of the patent law. Applicant appreciates the Examiner's recognition that a PBR application by itself would not be an enabled publication. Yet in essence, the Examiner is asserting that a non-enabling published description of a claimed invention combined with the sale of that invention outside of the United States would be enough to satisfy an anticipation rejection under 35 USC § 102(b).

Such a position is untenable under United States law. By way of example, a simple (non-enabling) listing of a product (such as a computer) in a catalog or magazine published one year before an application for patent in the United States combined with the sale of that computer outside the United States more than one year before application date would be enough to bar patent protection in our country. Such an assertion is ludicrous and the ramifications are endless if the Board chooses to change precedent and decide that a PBR application combined with the sale of a begonia named 'Nadine' in The Netherlands would be enough to bar patent protection in the United States.

III. Anticipation of plant subject matter

The cases of <u>In re LeGrice</u>, 301 F.2d 929, 133 USPQ 365 (CCPA 1962) and <u>Ex parte Thomson</u>, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992) are consistent with <u>Samour</u>, <u>Donohue</u>, and <u>Bristol-Myers</u> and do not support a proposition that a non-enabling publication about a plant may be made enabling by public use or sale of the plant itself.

A. In re LeGrice

At issue in <u>LeGrice</u> was whether a published catalog listing a variety of rose plants along with some botanical data and a color picture thereof barred patenting of that rose variety as a plant patent. It was established on the record that the color picture in the prior art catalog publication established identity at least in appearance between the rose plant illustrated in the catalog and the claimed variety.

1. A plant cannot be produced from a disclosure thereof in a printed publication.

In determining whether the catalog was an "enabling" disclosure, i.e., sufficient to give the public possession of the rose plant, the <u>LeGrice</u> court pointed out the following unique characteristics of plants as compared to manufactured articles. Plants protected by United States plant patents are asexually reproduced wherein the plant is propagated by divisions or cuttings to form clones, each of which is identical to its parent plant and to all other cuttings or clones taken from the parent plant. <u>Id.</u> at 937, 133 USPQ at 372. Even when the parentage of the claimed variety is set forth in a publication, no two seeds produced by cross-pollinating the parent plants can be expected to produce identical plants. <u>Id.</u> at 938, 133 USPQ at 373. The principles of heredity and plant genetics introduce innumerable possible combinations of genetic material which may result in equally innumerable distinct plants. <u>Id.</u>

The impossibility of producing a particular variety from a description thereof in a printed publication was a critical factor for the court in <u>LeGrice</u>. The court emphasized that the description of the invention in the printed publication must be an "enabling" description and that the proper test of an enabling description in a publication as a bar to a

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patent under § 102(b) is "whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought". <u>Id.</u> at 939, 133 USPQ at 374.

To put an invention in possession of the public based on a printed publication, the description therein must be:

so precise and particular that any person skilled in the art to which the invention belongs can construct and operate it without experiments and without further exercise of inventive skill.

Id. at 933, 133 USPQ at 369.

In 1962, the <u>LeGrice</u> court recognized that the knowledge of plant genetics made it impossible to reproduce a particular plant having specific botanical characteristics based solely on a description of the plant, even when the parent plants were known. Despite the many advances in biotechnology over nearly 40 years, that limitation on reproducing plants holds true.

Accompanying the Response of February 20, 2003 as Attachment A is a Declaration by Dr. Richard Craig, an expert in the field of horticulture. The details of Dr. Craig's Declaration are not repeated herein, but should be appreciated for the explanation of the differences between asexually reproduced plants and sexually reproduced plants and the impossibility of generating a desired plant from a description thereof in a printed publication. As detailed in Dr. Craig's Declaration, there is no possibility of recreating a particular variety via experimentation because of the endless possibilities when the genes of parent plants are combined to produce daughter plants.

Thus, when one makes a cross-fertilization of heterozygous parents, one cannot predict the specific combination of traits in the progeny. When a large number of genes have different allelic combinations in the parents, the possible genotypic combinations in the hybrid progeny approach infinity.

Craig Declaration at page 3.

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Dr. Craig states that a description of a plant (such as the description in a PBR) cannot be used to recreate the plant.

Starting only from a photograph or a written description of a particular cultivar, a plant breeder cannot reproduce the cultivar. No person can independently create through fertilization and hybridization the exact genetic replica of another plant.

Craig Declaration at page 4.

Thus, it is still true today that a description of a particular variety cannot enable one skilled in the art to recreate that variety.

In the decision below <u>LeGrice</u>, the Board of Appeals reasoned that since a description of a plant in a plant patent application is deemed sufficiently enabling to grant a patent, then a publication on a plant should be considered equally enabling to bar patenting. The <u>LeGrice</u> court pointed to two errors in that reasoning. First, § 162 specifically permits varying degrees of description in a plant patent while § 102(b) makes no such allowance regarding the sufficiency of the description in an anticipatory printed publication. Therefore, a plant patent application may be less specific than an anticipatory publication. Second, § 163 does not grant a right to exclude others from "making" a claimed plant but only to exclude others from asexually reproducing or selling the claimed plant. The statute reflects the reality that "there is no possibility of producing the plant *from a disclosure* as 35 U.S.C. § 112 contemplates" because one cannot make a plant, only asexually reproduce or sell it. <u>Id.</u> at 944, 133 USPQ at 378.

2. The description of a plant and identification of a source to obtain the plant outside the United States is not prior art under 35 U.S.C. § 102(b) in a plant patent application.

In the present case, the Examiner has asserted that <u>LeGrice</u> is not controlling because it did not specifically address the issue of enablement of a printed publication on a plant variety by sale of that plant outside the United States. However, as detailed below, the appeal in <u>LeGrice</u> actually did address an issue of commercial availability of a plant outside the United States.

3. The <u>LeGrice</u> decision contains significant evidence of public distribution of the rose varieties.

The Appellant of <u>LeGrice</u>, (Mr. Edward Burton LeGrice) filed plant patent applications in the United States in 1958 on two rose varieties, Charming Maid and Duskey Maiden. More than one year before the filing dates, both varieties were listed in the National Rose Society Annual of England and in catalogs. Those publications are compelling evidence of public use or sale of the varieties in England.

The Rose Annual of 1949 stated that Dusky Maiden, "raised and exhibited by E.B. LeGrice", received "The Gold Medal Award". <u>Id.</u> at 931, 133 USPQ at 368. An award-winning plant undoubtedly was exhibited to rose breeders and other skilled artisans. Certainly, Dusky Maiden was publicly used in England by 1949.

The Rose Annual of 1954 contained information on Charming Maid including listing the following: "Raiser and Distributor E.B. LeGrice, Note Walsham". <u>Id.</u> at 932, USPQ at 368. According to the 1954 Rose Annual, Charming Maid was distributed by Mr. LeGrice. Distribution (via a sale or other public activity) of Charming Maid occurred in England more than one year before the United States filing date.

Both Dusky Maiden and Charming Maid were described and shown in catalogs with color photographs thereof establishing identity in appearance between the varieties in the catalogs and the varieties of the United States plant patent applications. *Id.* Presentations of the varieties in a catalog is also compelling evidence of their status of having been offered for sale in England.

Despite all this evidence of sale and/or public use of Dusky Maiden and Charming Maid by Mr. LeGrice in England, the appeals court did not specifically address any issue of such activity presumably because it occurred outside the United States.

4. The record of the appeal in <u>LeGrice</u> shows that the sale and/or public use of the two rose varieties was disposed by the Board.

There was no discussion about enablement of the printed publication based on public availability of the rose in the <u>LeGrice</u> decision reported by the CCPA because the issue of public availability of the roses outside the United States was disposed of in the lower {woo85319.1}

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decision at the Board of Appeals. See, <u>Application of Edward Burton LeGrice</u>, Decision of Board of Appeals, February 12, 1960 (attached hereto and hereinafter referred to as the "Board LeGrice Decision").

In the appeal to the Board by Mr. LeGrice, the Board correctly recognized that the "use or sale of the plants in a foreign country would be irrelevant" to the issue of novelty. Id. at page 25. Moreover, the Board found evidence of foreign sale and/or public use of the rose varieties.

The publications indicated that the particular plants were on sale, and presumably also in public use, more than one year prior to the respective filing dates of the applications since appellant is indicated as 'raiser and distributor.' However this question is not in issue since the public use or sale must be in the United States in order to bar a patent and these events, as far as anything suggested by the record is concerned, took place in England. The single broad issue of the competency of a prior printed publication to bar a plant patent is presented.

Id. at page 22.

Hence, the <u>LeGrice</u> court had plenty of evidence of commercial availability of the rose varieties outside the United States, and the stated presumption was that the plant was in public use. It did not directly address those facts since they were irrelevant to the novelty of the plant under United States statutory law and had been properly dispensed with by the Board of Appeals.

5. A publication is incapable of placing a plant variety in the public domain.

The <u>LeGrice</u> court focused on whether the publications (the Rose Annuals or the catalogs), when interpreted in light of the knowledge possessed by plant breeders, placed the rose varieties in the public domain. Importantly, when the court looked to what constituted the knowledge possessed by plant breeders, it did not even consider the evidence of prior use and/or sale of the rose varieties. The Board had dismissed any relevance of that evidence to the issue of novelty of the rose varieties in the United States.

Instead, the standard applied by the <u>LeGrice</u> court for the enablement of a publication under 35 U.S.C. § 102(b) is whether "a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention". <u>LeGrice</u> at 936, 133 USPQ at 372. The "knowledge" for a skilled artisan was not -- and still is not -- the commercial activity of the breeder outside the United States.

The "knowledge" of the skilled plant breeder includes plant genetics. In 1962, the knowledge of plant genetics meant that publications (such as the Rose Annuals and catalogs) could not be relied upon as statutory bars under 35 U.S.C. § 102(b). The <u>LeGrice</u> court cautioned, however, that each case must be decided on its own facts and that future studies may add to "the knowledge of plant breeders so that they may *someday* secure possession of a plant invention by a description in a printed publication". <u>Id.</u> at 939, n. 7, 133 USPO at 374, n. 7.

There can be no dispute; that "someday" has not yet arrived.

6. The facts of <u>LeGrice</u>, non-enablement of a plant patent claim by a description of the plant, parallel the present case.

In both <u>LeGrice</u> and here, the material elements of a plant patent claim are not set forth in the printed publication and there is no need to consult additional references, nor is it appropriate to do so.

A PBR application which refers to a species of a plant, a plant name and a few bits of botanical data cannot be considered to be so "precise and particular" that a skilled artisan could "construct and operate it without experiments and without further exercise of inventive skill." The ability to purchase a begonia named 'Nadine' one year prior to the application filing date is not equivalent to the ability to "construct and operate" a new begonia variety named 'Nadine' based on the PBR application. One skilled in the art may have learned of a begonia named 'Nadine' – outside the United States. While public prior use and sale are avenues by which a plant enters the public domain, that prior use or sale must have occurred in the United States to rise to the level of a statutory bar. See 35 U.S.C. § 102(b).

A PBR application could lead one skilled in the art to find a plant to purchase outside the United States which bears a name mentioned in the PBR application. That scenario is not one which renders the PBR application enabling. It is simply a trail which leads to a sale of a plant outside the United States. There is no support in <u>LeGrice</u> or elsewhere for the proposition that sale of a named plant outside the United States automatically enables the publication of a PBR application listing a plant with the same name.

B. Ex parte Thomson

Naturally, a different result was found in <u>Ex parte Thomson</u> when the claims in a utility application for a cotton cultivar were rejected over a prior art reference which identically disclosed the specification of the application for the cotton cultivar. The rejected claims were as follows:

- 1. A cotton cultivar having the designation Siokra (ATTC 40405).
- 2. Seeds of the cotton cultivar according to Claim 1.

The Board of Patent Appeals and Interferences found that several prior art references disclosed the exact same cotton cultivar and seeds of that cultivar. Importantly, the Board found that "for enablement purposes, the descriptive words of the specification herein do not differ substantially from the disclosures of the cited publications". Id. at 1621 (emphasis added). Moreover, the specification of the utility application was enabled by the availability of the claimed seeds deposited in the American Type Culture Collection (ATTC). The cited publications were also enabled by the public availability of the same cotton seeds. Id. As such, the public accessibility of the claimed seeds would have enabled the skilled artisan to make and use the claimed cotton cultivar and its seeds. Id. The Board upheld the rejection of the claims under 35 U.S.C. § 102(b) based on (1) prior art references that identically disclosed the claimed cultivar and (2) the opportunity for a skilled cotton grower to read the prior art references, purchase the commercially available seeds, and employ conventional techniques to obtain the claimed invention, namely, the plants and its seeds.

The Board distinguished <u>LeGrice</u> for three reasons.

First, actually following <u>LeGrice</u>, it recognized that each case is decided upon its own facts in determining whether the description in a printed publication is "adequate to put the public in possession of the invention and bar patenting of a plant" under § 102(b). <u>Id.</u> at 1620. The Board believed that sufficient advancements in plant eugenics warranted not following <u>LeGrice</u>'s rule on non-enablement of publications and expressed no doubt that the skilled artisan would be able to grow the claimed cultivar. As detailed in Dr. Craig's Declaration, the Board was clearly mistaken. The "someday" of securing a plant invention by a description in a printed publication has not yet arrived. Regardless of the Board's erroneous comments on genetic technology, it remains axiomatic that each case must be decided on its own facts. <u>Id.</u>

Moreover, the <u>Thomson</u> Board clearly misunderstood the evidence of commercial availability of the rose varieties in <u>LeGrice</u> by stating that:

[LeGrice's] holding was based on the specific "printed publications" before it, and no indication was given that the "prior catalogue publication" before it evidenced commercial availability in a readily enabling form. The court simply stated that the prior catalog publication "includes a color picture of the rose clear enough to establish identity in appearance between the rose illustrated and applicants variety".

Thomson, 24 USPQ2d at 1621.

As detailed above, the <u>LeGrice</u> decision is replete with evidence of public use and/or sale of the rose varieties outside the United States. The irrelevance of those activities was disposed of by the Board.

Second, the Board found it significant that for enablement purposes the descriptive words of the specification did not differ substantially from the disclosures of the cited publications. <u>Id.</u> In other words, all the material elements of the claim were disclosed in the primary reference. The specification was enabled by the deposit of the claimed seeds and the cited publications were also enabled by the deposit of the same seeds. The court noted that <u>LeGrice</u> did not consider the public availability of the rose plant at issue therein, {woo85319.1}

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Attorney Docket No. 2475-010559

and that the <u>LeGrice</u> holding was based on the specific printed publications. Public availability of the plant was one factor in the <u>Thomson</u> decision because the claim itself was enabled by public availability of the plant. However, a "significant" aspect of the 102(b) rejection was that the descriptive words of the prior art references did "not differ substantially" from the disclosures of the specification. <u>Id.</u>

Finally, the Board pointed out that whereas <u>LeGrice</u> was directed to patentability of plant patents, the patent at issue in <u>Thomson</u> was a utility patent which is afforded a broader scope of protection. <u>Id.</u> at note 1. Hence, the standard for anticipation by a printed publication is to be more broadly applied to the claims in a utility application than to a claim in a plant patent application. <u>Id.</u>

The Office Action in the present case incorrectly asserts that the same question was asked in <u>Thomson</u> and <u>LeGrice</u> of "what is required to enable" a printed publication describing a plant. The questions in those two cases must be different because <u>Thomson</u> involved a utility patent claim and <u>LeGrice</u> involved a plant patent claim -- and those are two different forms of statutory subject matter having different standards for enablement and infringement.

It should be understood that the <u>Thomson</u> decision is consistent with <u>Donohue</u> and <u>Samour</u> in meeting the requirements for using additional references in a § 102(b) rejection.

First, every material element of the <u>Thomson</u> claim was set forth in the primary reference. ("We find it significant for enablement purposes the descriptive words of the specification do not differ substantially from the disclosure of the cited publications"). Thomson, 24 USPQ2d at 1621.

Second, the additional "reference" (the publicly available seeds) was cited solely to show that the plant described fully in the primary reference was in the public domain. As was true for <u>Samour</u> and <u>Donohue</u>, the Thomson rejection did not combine teachings of two references. The added reference only demonstrated that the plant material fully described in the primary reference was in the public domain.

IV. Enablement of a PBR publication as a prior art reference is inconsistent with past and current examination practices in plant patent applications.

The standards for compliance with 37 C.F.R. § 1.163 and 35 U.S.C. § 112, first paragraph in plant patent applications have become increasingly strict. Despite the variance in the degree of description in a plant permitted by 35 U.S.C. § 162, recent experience shows that many disclosures of plant patent applications are objected to and the claims therein are rejected under 35 U.S.C. § 112 first and second paragraphs which require as follows (emphasis added):

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to **enable** any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The May 3, 2002 Office Action in the present application included an objection to the disclosure under the first paragraph of § 112 and a rejection of the claim under the first and second paragraphs of § 112 for asserted lack of "a full, clear, and complete botanical description of the plant and the characteristics which define same per se and which distinguish the plant from related known cultivars and antecedents".

Historically, the United States Patent and Trademark Office has not considered the information in a PBR application sufficient under §§ 112 and 162. More recently, even significantly more complete disclosures (such as the original specification filed herein) are not considered to be sufficiently complete (not enabling) under the statute.

To now assert that a PBR application somehow is enabling prior art (alone or in combination with sale or use outside the United States) is inconsistent with the examination practice of requiring detailed botanical information in plant patent applications. The United States Patent and Trademark Office cannot have it both ways of asserting a PBR

application as enabling prior art and rejecting reasonably detailed plant patent applications for lack of enablement. Moreover, this new interpretation of PBR applications as being enabling prior art is contrary to decades of plant patent examination policy and practice.

Future plant patent applicants can comply with the stricter interpretation of § 162 when submitting their applications, but they should not be faced with a prior art rejection based on a non-enabling PBR document.

IX

THE REALITIES OF PLANT BREEDING

Time delays in breeding new plant varieties exist whether the breeding occurs in the United States or elsewhere. In the case of plants bred outside the United States, additional testing and trialing in the United States must take place to make sure the new plants are adaptable to the climatic conditions in this country. This often takes several years before the plants are deemed acceptable and actually enter the United States market. Only a few varieties tested and trialed in the United States actually enter the United States market, and it is not economically feasible to file immediately on every variety to be tested. The new patent policy requires that such immediate filing take place thereby placing the foreign plant patent breeder at a distinct economic disadvantage.

A plant bred in The Netherlands can be introduced much more quickly in The Netherlands because it was bred and grown there from the outset. Therefore, there is often a sale in Europe more than one year before the United States plant patent application is filed. A sale outside the United States does not trigger a statutory patent bar and does not diminish the need to afford protection to foreign plant breeders seeking to introduce their horticultural developments into the United States.

This concept has been understood since at least the time that the Townsend-Purnell Plant Patent Act become law in 1930. The Plant Patent Act of 1930 was enacted "to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry." H.R 1129, 71st Congress, 2d Session (1930).

Today the plant breeder has no adequate financial incentive to enter upon his work. A new variety once it has left the hands of the breeder may be reproduced in unlimited quantity by all. The originator's only hope of financial reimbursement is through high prices for the comparatively few reproductions that he may dispose of during the first two or three years. After that time, depending on the speed with which the plant may be asexually reproduced, the breeder loses all control of his discovery. Under the bill the originator will have control of his discovery during a period of 17 years, the same term as under industrial patents. If the new variety is successful, the breeder or discoverer can expect an adequate financial reward.

Id.

Under the current examination practice, rejection of plant patent applications by foreign breeders who have not yet introduced their discoveries into the United States cuts off their opportunities of reaping adequate financial reward in the United States. Plant varieties which are not ready for introduction into the United States, but were sufficiently developed in Europe to be introduced there, are not given the benefit of the patent system as was intended by the Plant Patent Act of 1930. Without that benefit, foreign plant breeders "only hope of financial reimbursement is through high prices for the comparatively few reproductions that [they] may dispose of during the first two or three years" following introduction of varieties into the United States. Id. The Plant Patent Act of 1930 was adopted so that "plant patents will mean better agricultural products that will give the public more actual value for its dollar". Due to the current rejection policy and to the detriment of the public, advances in agriculture made outside the United States may not reach this country.

This policy by the United States Patent and Trademark Office represents a radical departure from any previous policy in the area of plant patent law. It has been estimated that under such a radical policy, 70% of the extant plant patents issued to foreign applicants in the United States are invalid.

Relying on use and sales outside the United States to turn a non-enabling plant disclosure into an enabling one was never contemplated by drafters of the Plant Patent Act, is

not recognized by statute, is contrary to Patent Office policy from at least as early as the <u>LeGrice</u> decision (1962) and makes absolutely no sense to anyone skilled in the art. This new radical policy needs to be promptly reversed so foreign plant breeders again have opportunities in this country to file United States plant patent applications.

X CONCLUSION

In the absence of disclosure of every material element of the claimed subject matter, the PBR document fails to meet the anticipation requirements of 35 U.S.C. § 102(b). The sale of the claimed variety outside the United States more than one year prior to the filing date of the United States patent application can be relied upon only to show that the claimed subject matter was in the possession of the public and not to supplement the impossibility of a PBR application to disclose every material element of the claimed invention.

The plant patent examining group has created a new position on prior art to plant patent applications that is counter to decades of examination. This policy, if not withdrawn, will have the effect of essentially blocking United States plant patents on plant varieties discovered in foreign countries. It represents the ultimate disservice to the foreign breeder.

This new position has no basis in fact or in law and is based in part on a false premise, namely, that <u>LeGrice</u> did not deal with sale in a foreign country. According to statute, the sale puts the variety in a certain public domain, but not the public domain which constitutes a statutory bar - it is not "in this country" as required by 35 U.S.C. § 102(b). Moreover, the "someday" of plant genetics from <u>LeGrice</u> has not arrived. A printed publication cannot bar patenting of a plant because a plant variety cannot be created from a description of the plant.

The only § 102(b) bar to plant patent applications is the sale, offer for sale, or public use of the plant itself within the United States. Likewise, the invention of a plant patent is the plant itself. A plant patent can have but one claim -- to the plant itself. Plant

patent infringement requires proof that the infringing plant is an asexually reproduced progeny of the parent plant -- it requires access to the plant itself. <u>Imazio Nursery, Inc. v. Dania Greenhouses</u>, 69 F.3d 1560, 36 USPQ2d 1673 (Fed. Cir. 1995).

It follows that the plant itself must be present in the United States to bar novelty under §102(b). The asserted enablement of a printed publication by "non-prior art" (sale outside the United States) is an attempt to thwart the statutory requirement that the plant itself be present in the United States to bar a plant patent in light of today's understanding of plant genetics. The anticipation rejection should be withdrawn.

A check in the amount of \$330.00 accompanies this Appeal Brief. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees which may be required to Deposit Account No. 23-0650. Please refund any overpayments to Deposit Account No. 23-0650. An original and two copies of this Appeal Brief are enclosed.

Respectfully submitted,

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APPENDIX A

I Claim:

1. A new and distinct variety of begonia plant substantially as shown and described.

OCT 1 7 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

10/008,292

Applicant

Jan Man

Filed

November 13, 2001

Title

BEGONIA PLANT NAMED

'NADINE'

Group Art Unit

1661

Examiner

Kent L. Bell

APPEAL BRIEF

MAIL STOP APPEAL BRIEF – PATENTS Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Appeal Brief is submitted in support of the Notice of Appeal filed on August 14, 2003 appealing the final rejection of claim 1.

The headings used hereinafter and the subject matter set forth under each heading are in accordance with 37 C.F.R. § 1.192(c).

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on October 14, 2003.

Theresa Ulinski

(Name of Person Mailing Paper)

Signature

Date

I

REAL PARTY IN INTEREST

Begonia Breeders Associates B.V. is the Assignee of the entire right, title, and interest to the above-identified application and, as such, is the real party in interest in this Appeal.

 \mathbf{II}

RELATED APPEALS AND INTERFERENCES

Other Appeals known to the Appellant, the Appellant's legal representative, or the Assignee of the present application which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal include Appeals filed in the following applications assigned to the Assignee of the present application: 10/012,139; 10/010,496 and 10/007,711. Appellant's legal representative is handling other such Appeals for other Applicants/Assignees and is also aware of other Appeals handled by other legal representatives directed to the same issue.

There are no interferences known to the Appellant, the Appellant's legal representative, or the Assignee of the above-identified application which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

Ш

STATUS OF CLAIMS

Claim 1 is finally rejected under 35 U.S.C. § 102(b) for anticipation by Plant Breeder's Rights Application No. BGN0268 (The Netherlands) in view of a sale of a plant named 'Nadine' in The Netherlands on November 1, 1999;

Claim 1 is reproduced in Appendix A which is attached hereto.

IV

STATUS OF AMENDMENTS

No response after the final Office Action dated May 14, 2003 has been submitted in this case. There was no claim change made after the final Office Action. The claim on appeal is the claim as filed with the application on November 13, 2001 which refers to the specification and drawing, the specification having been amended by the Amendments of August 5, 2002 and February 20, 2003.

 \mathbf{V}

SUMMARY OF THE INVENTION

The claim on appeal in the present application is directed to a variety of begonia named 'Nadine' which is described in detail on four pages of the specification and illustrated in a photograph. The claimed variety is a selection from a population of seedlings resulting from a mutation of its parent cultivar and possesses all of the botanical characteristics fully described and shown in the present application.

VI

ISSUE PRESENTED

The following issue is presented in this Appeal:

Is claim 1 anticipated by a foreign Plant Breeder's Rights (PBR) Application in view of a sale of a variety of begonia named 'Nadine' outside of the United States in 1999?

VII

GROUPING OF CLAIMS

There is a single claim in the application, claim 1, and no grouping is applicable.

VIII

ARGUMENTS

I. An anticipation rejection cannot be built from multiple references.

The sale of a variety of begonia named 'Nadine' outside the United States only indicates that a begonia plant was in the possession of the public one year prior to the patent application filing date. To the extent that the sold variety was the same as the claimed variety, such a sale outside the United States is not a statutory bar under 35 U.S.C. § 102(b) which prohibits patenting of an invention which "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country".

Combining the sale of a claimed variety outside the United States with the scant disclosure in a PBR application constitutes improper use of prior art under 35 U.S.C. § 102(b) to build an "anticipation" rejection. It is well-settled that teachings of multiple references may not be combined to build an anticipation rejection. <u>Studiengesellschaft Kohle, M.B.H. v. Dart Industries, Inc.</u>, 726 F.2d 724, 727, 220 USPQ 841, 842 (Fed. Cir. 1984).

The anticipation rejection in the present application has been characterized as based on the cited PBR document. According to the Examiner, the cited PBR document teaches every material element of the claim, despite its severe lack (or absence) of botanical information. The sale of a plant named 'Nadine' outside the United States supposedly is used to show that the plant disclosed in the PBR document was in the public domain more than one year prior to the application filing date.

The rejection is flawed in its reliance on a publication which does not disclose every material element of the claim and its attempt to circumvent 35 U.S.C. § 102(b) to reject a claim on an invention that may have been sold outside the United States.

The Office Action of November 20, 2002 recognizes that a publication which is relied upon as prior art under 35 U.S.C. § 102(b) must be enabling. Moreover, it is admitted at page 6 of that Office Action that a PBR application "by itself would not be an enabled publication, were the plant not in the public domain". To account for the deficient teachings of a PBR application, namely, the inability of a PBR application to enable the claimed plant, the rejection is supplemented by possible prior public availability of the claimed plant. The November 20, 2002 Office Action asserts that In re Samour, 571 F.2d 559, 197 USPQ1 (CCPA 1978) and In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) support this rejection. Application of that case law to the present case is inappropriate.

The following comments set forth the proper standards for using multiple references in a § 102(b) rejection, namely, how an additional printed publication (a true § 102(b) reference) may be used to show that anticipatory prior art is in the public domain.

II. Use of multiple references to make a rejection under 35 U.S.C. § 102(b)

It is well-established that a printed publication which discloses "every material element of the claimed subject matter" constitutes a bar under 35 U.S.C. § 102(b) if more than one year prior to an application's filing date, it placed the claimed subject matter "in possession of the public". In re Samour, 571 F.2d at 562, 197 USPQ at 3. See also, In re Donohue, 766 F.2d at 533, 226 USPQ at 621 ("It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it".)

A. Anticipation rejections based on multiple references require a primary enabling disclosure and a second written reference.

There is some flexibility in the rule that only one reference may be used in an anticipation rejection. An additional reference may be used to prove that the primary reference discloses subject matter which is in the public's possession. MPEP § 2131.01. Pursuant to this exception, a secondary reference may be included in an anticipation rejection only when the primary reference in and of itself is an enabling disclosure. An additional

reference may be used to show what the primary reference contains -- and not to supplement what the primary reference lacks. In both of <u>In re Samour</u> and <u>In re Donohue</u> (each relating to patent applications on chemical inventions), an additional written reference was relied upon to show that the subject matter of a primary reference was available to the public. Neither case stands for the proposition that an additional reference may be used to supplement a non-enabling disclosure of a primary reference.

The claim at issue in <u>In re Samour</u> was directed to a specific chemical compound with the structure appearing in the claim. A first prior art reference disclosed the structural formula set forth in the claim, but the reference did not disclose a method for its preparation. Hence, the applicant argued that the first reference was non-enabling. In response, the Examiner cited an additional reference which disclosed a method for preparing similar types of compounds. On appeal from a final rejection, the Patent and Trademark Office Board of Appeals agreed that the additional reference provided a legally sufficient teaching of how to make the compound disclosed in the first reference. The court agreed that the mere recitation of the chemical formula of the claimed composition in a prior art reference would not have been sufficient to place the compound in the public's possession. Yet, the court was willing to consider relying on additional references:

... [s]olely as evidence that, more than one year prior to appellant's filing date, a method of preparing the claimed subject matter (DMMP) would have been known by, or would have been obvious to, one of ordinary skill in the art. Therefore, the key issue before us is whether the PTO, in making a rejection under 35 USC § 102(b) on a single prior art reference that discloses every material element of the claimed subject matter, can properly rely on additional references for such purpose.

Id. at 562, 197 USPQ at 4 (emphasis added).

The court maintained the rejection of the claim for the chemical compound based on the combined teachings of the printed publication disclosing the compound and a reference which disclosed a method for making similar compounds explaining that the additional reference cited in the § 102(b) rejection was "not relied on for a suggestion or incentive to combine teachings to meet the claimed limitations" (as in a rejection under 35

U.S.C. § 103), but, rather, to show that the claimed subject matter, every material element of which is disclosed in the primary reference, was in the possession of the public. <u>Id.</u> at 563, 197 USPQ at 4.

The <u>Samour</u> court did not import any disclosure from the secondary reference into the disclosure of the primary reference which taught every material element of the claimed compound. Every material element of the claim was the structural formula of the claimed compound. The primary reference disclosed that same structural formula. The secondary reference was only used to demonstrate that the claimed subject matter, which was fully disclosed in a printed publication, was available to the public.

A similar reasoning and result was found in <u>In re Donohue</u> where a claim also directed to a set of chemical compounds was rejected for anticipation by a primary reference that did not disclose methods of preparing the claimed compounds. Additional references relied upon by the United States Patent and Trademark Office taught how such compounds could be produced. The legal basis for upholding the rejection was outlined as follows:

It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. In re Sasse, 629 F.2d 675, 681, 207 USPQ 107, 111 (CCPA 1980); In re Samour, 571 F.2d at 562, 197 USPQ at 4; see also Reading & Bates Construction Co. v. Baker Energy Resources Corp., 748 F.2d 64, 651-52, 223 USPQ 1168, 1173 (Fed. Cir. 1984). Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. See In re LeGrice, 301 F.2d at 939, 133 USPQ at 373-74. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling. In re Borst, 345 F.2d 851, 855, 45 USPQ 554, 557 (CCPA 1965), cert. denied, 382 U.S. 973, 148 USPQ 771 (1966).

Id. at 533, 226 USPQ at 621 (footnote deleted).

The court specifically followed the rule of <u>Samour</u> to determine that the claimed subject matter was in the public's possession by looking to additional references.

The additional references utilized in this case (viz., Lincoln and Wagner) are not relief [sic] upon for suggestion or motivation to combine teachings to meet the claim limitations, as in rejections under 35 U.S.C. § 103. *In re Samour*, 571 F.2d at 563, 197 USPQ at 4-5. Such reliance would be pointless because Nomura [the primary reference] discloses every element claimed. The purpose of citing Lincoln and Wagner is, instead, to show that the claimed subject matter, as disclose [sic] in Nomura, was in the public's possession.

<u>Id.</u>

Both In re Samour and In re Donohue involved claims to a class of chemical compounds that was fully disclosed in a prior art reference. The secondary references (printed publications) in both cases were not employed to supplement any need for additional disclosure not present in the primary reference so that one skilled in the art could comprehend the scope of that referenced disclosure but only to show that the claimed chemical compounds were within the public domain. In other words, on their faces, the primary references were "enabling" because they taught every material element of the claimed subject matter. The only reliance on a secondary reference was to show that the claimed subject matter was in the public's possession one year prior to the filing date of the patent applications for the chemical compounds.

This line of case law was recently followed in <u>Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. et al.</u>, 246 F.3d 1368, 58 USPQ2d 1508 (Fed. Cir. 2001). Ben Venue and its codefendants alleged invalidity of a patent obtained by Bristol-Myers for a method of treating a cancer patient having steps of (i) premedicating the patient with a first drug and (ii) administering a second drug. The defendants argued that Bristol's claim was anticipated by a prior art reference which not only described treating patients with the second drug (i.e., the second step) but also suggested that "[f]urther studies are needed to see if *pretreatment regimens* [i.e., the first step], ... will permit the safe administration of this compound". <u>Id.</u> at 1372, 58 USPQ2d at 1515-1516. At issue was whether the prior art reference which mentioned a pretreatment regimen was "enabling to one of skill in the art" one year before the filing date of Bristol's patent application based on additional references

and teachings to pretreat cancer patients. Following both <u>Samour</u> and <u>Donohue</u>, the court noted that enablement of an anticipatory reference may be demonstrated by another reference (as in <u>Samour</u> and <u>Donohue</u>, a printed publication) and restated the requirement of "a showing of each limitation of a claim in a single reference" for anticipation. <u>Id.</u> The court concluded that it was proper to look at other references to establish that the pretreatment regimen mentioned in the primary reference was in the public domain one year prior to Bristol's filing date. As was true for the claims at issue in <u>Donohue</u> and <u>Samour</u>, every material element of the claim in <u>Bristol-Myers</u> was present in the primary reference, namely, (i) premedicating a patient with a first drug and (ii) administering to the patient a second drug. The primary reference contained both of those limitations and additional printed publications were only relied upon to show that premedicating a patient was within the public domain one year prior to the filing date of the patent application. No subject matter from the secondary reference was used to supplement the disclosure of the primary reference.

Hence, there are two requirements for using an additional reference to "enable" a primary reference in forming an anticipation rejection.

- 1. The primary reference must contain "every material element of the claimed invention"; and
- 2. The additional reference (a printed publication) is relied upon only to demonstrate that the claimed subject matter was in the possession of the public one year prior to the filing date of the patent application.
- B. Sale of patentable subject matter outside of the United States is not a prior art "reference" and cannot be used to enable another reference under 35 U.S.C. § 102(b).

It is elementary chemistry to realize that the disclosure of a compound's formula is enough to anticipate the claimed chemical formula because that formula is indeed the entire invention. The <u>Samour</u> and <u>Donohue</u> courts agreed that a secondary piece of prior art (a written publication) could be used to show the state of the art in the chemical field was

in the public's possession. However, disclosure of the botanical name (and possibly a few other particulars) of a new and unanticipated asexually reproduced plant variety is not enough to anticipate a plant patent for the claimed variety.

In the present application, the Examiner relies on <u>Samour</u> and <u>Donohue</u> to support a position that the sale of a variety named 'Nadine' in The Netherlands is some type of "reference" that indicates what knowledge was in the public domain. However, this line of cases permits use of a true reference, an additional piece of prior art (a pre-application filing date publication), as evidence of the knowledge in the public domain. The sale of an invention outside the United States is not such a reference.

It is contrary to longstanding tenets of the patent laws to assert that sale of a claimed invention outside of the United States qualifies as a reference at all. The sale of a variety named 'Nadine' outside the United States is not prior art. It is not a reference which is appropriate to use as evidence of the public's knowledge. An assertion that the sale of a claimed invention outside the United States as a reference (per Samour and Donohue) would vitiate the meaning of the on-sale bar of 35 U.S.C. § 102(b).

If the Examiner's position is maintained, it would be changing the landscape of the patent law. Applicant appreciates the Examiner's recognition that a PBR application by itself would not be an enabled publication. Yet in essence, the Examiner is asserting that a non-enabling published description of a claimed invention combined with the sale of that invention outside of the United States would be enough to satisfy an anticipation rejection under 35 USC § 102(b).

Such a position is untenable under United States law. By way of example, a simple (non-enabling) listing of a product (such as a computer) in a catalog or magazine published one year before an application for patent in the United States combined with the sale of that computer outside the United States more than one year before application date would be enough to bar patent protection in our country. Such an assertion is ludicrous and the ramifications are endless if the Board chooses to change precedent and decide that a PBR application combined with the sale of a begonia named 'Nadine' in The Netherlands would be enough to bar patent protection in the United States.

III. Anticipation of plant subject matter

The cases of <u>In re LeGrice</u>, 301 F.2d 929, 133 USPQ 365 (CCPA 1962) and <u>Ex parte Thomson</u>, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992) are consistent with <u>Samour</u>, <u>Donohue</u>, and <u>Bristol-Myers</u> and do not support a proposition that a non-enabling publication about a plant may be made enabling by public use or sale of the plant itself.

A. In re LeGrice

At issue in <u>LeGrice</u> was whether a published catalog listing a variety of rose plants along with some botanical data and a color picture thereof barred patenting of that rose variety as a plant patent. It was established on the record that the color picture in the prior art catalog publication established identity at least in appearance between the rose plant illustrated in the catalog and the claimed variety.

1. A plant cannot be produced from a disclosure thereof in a printed publication.

In determining whether the catalog was an "enabling" disclosure, i.e., sufficient to give the public possession of the rose plant, the <u>LeGrice</u> court pointed out the following unique characteristics of plants as compared to manufactured articles. Plants protected by United States plant patents are asexually reproduced wherein the plant is propagated by divisions or cuttings to form clones, each of which is identical to its parent plant and to all other cuttings or clones taken from the parent plant. <u>Id.</u> at 937, 133 USPQ at 372. Even when the parentage of the claimed variety is set forth in a publication, no two seeds produced by cross-pollinating the parent plants can be expected to produce identical plants. <u>Id.</u> at 938, 133 USPQ at 373. The principles of heredity and plant genetics introduce innumerable possible combinations of genetic material which may result in equally innumerable distinct plants. <u>Id.</u>

The impossibility of producing a particular variety from a description thereof in a printed publication was a critical factor for the court in <u>LeGrice</u>. The court emphasized that the description of the invention in the printed publication must be an "enabling" description and that the proper test of an enabling description in a publication as a bar to a {woo85319.1}

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patent under § 102(b) is "whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought". <u>Id.</u> at 939, 133 USPQ at 374.

To put an invention in possession of the public based on a printed publication, the description therein must be:

so precise and particular that any person skilled in the art to which the invention belongs can construct and operate it without experiments and without further exercise of inventive skill.

Id. at 933, 133 USPQ at 369.

In 1962, the <u>LeGrice</u> court recognized that the knowledge of plant genetics made it impossible to reproduce a particular plant having specific botanical characteristics based solely on a description of the plant, even when the parent plants were known. Despite the many advances in biotechnology over nearly 40 years, that limitation on reproducing plants holds true.

Accompanying the Response of February 20, 2003 as Attachment A is a Declaration by Dr. Richard Craig, an expert in the field of horticulture. The details of Dr. Craig's Declaration are not repeated herein, but should be appreciated for the explanation of the differences between asexually reproduced plants and sexually reproduced plants and the impossibility of generating a desired plant from a description thereof in a printed publication. As detailed in Dr. Craig's Declaration, there is no possibility of recreating a particular variety via experimentation because of the endless possibilities when the genes of parent plants are combined to produce daughter plants.

Thus, when one makes a cross-fertilization of heterozygous parents, one cannot predict the specific combination of traits in the progeny. When a large number of genes have different allelic combinations in the parents, the possible genotypic combinations in the hybrid progeny approach infinity.

Craig Declaration at page 3.

Dr. Craig states that a description of a plant (such as the description in a PBR) cannot be used to recreate the plant.

Starting only from a photograph or a written description of a particular cultivar, a plant breeder cannot reproduce the cultivar. No person can independently create through fertilization and hybridization the exact genetic replica of another plant.

Craig Declaration at page 4.

Thus, it is still true today that a description of a particular variety cannot enable one skilled in the art to recreate that variety.

In the decision below <u>LeGrice</u>, the Board of Appeals reasoned that since a description of a plant in a plant patent application is deemed sufficiently enabling to grant a patent, then a publication on a plant should be considered equally enabling to bar patenting. The <u>LeGrice</u> court pointed to two errors in that reasoning. First, § 162 specifically permits varying degrees of description in a plant patent while § 102(b) makes no such allowance regarding the sufficiency of the description in an anticipatory printed publication. Therefore, a plant patent application may be less specific than an anticipatory publication. Second, § 163 does not grant a right to exclude others from "making" a claimed plant but only to exclude others from asexually reproducing or selling the claimed plant. The statute reflects the reality that "there is no possibility of producing the plant *from a disclosure* as 35 U.S.C. § 112 contemplates" because one cannot make a plant, only asexually reproduce or sell it. <u>Id.</u> at 944, 133 USPQ at 378.

2. The description of a plant and identification of a source to obtain the plant outside the United States is not prior art under 35 U.S.C. § 102(b) in a plant patent application.

In the present case, the Examiner has asserted that <u>LeGrice</u> is not controlling because it did not specifically address the issue of enablement of a printed publication on a plant variety by sale of that plant outside the United States. However, as detailed below, the appeal in <u>LeGrice</u> actually did address an issue of commercial availability of a plant outside the United States.

3. The <u>LeGrice</u> decision contains significant evidence of public distribution of the rose varieties.

The Appellant of <u>LeGrice</u>, (Mr. Edward Burton LeGrice) filed plant patent applications in the United States in 1958 on two rose varieties, Charming Maid and Duskey Maiden. More than one year before the filing dates, both varieties were listed in the National Rose Society Annual of England and in catalogs. Those publications are compelling evidence of public use or sale of the varieties in England.

The Rose Annual of 1949 stated that Dusky Maiden, "raised and exhibited by E.B. LeGrice", received "The Gold Medal Award". <u>Id.</u> at 931, 133 USPQ at 368. An award-winning plant undoubtedly was exhibited to rose breeders and other skilled artisans. Certainly, Dusky Maiden was publicly used in England by 1949.

The Rose Annual of 1954 contained information on Charming Maid including listing the following: "Raiser and Distributor E.B. LeGrice, Note Walsham". <u>Id.</u> at 932, USPQ at 368. According to the 1954 Rose Annual, Charming Maid was distributed by Mr. LeGrice. Distribution (via a sale or other public activity) of Charming Maid occurred in England more than one year before the United States filing date.

Both Dusky Maiden and Charming Maid were described and shown in catalogs with color photographs thereof establishing identity in appearance between the varieties in the catalogs and the varieties of the United States plant patent applications. *Id.* Presentations of the varieties in a catalog is also compelling evidence of their status of having been offered for sale in England.

Despite all this evidence of sale and/or public use of Dusky Maiden and Charming Maid by Mr. LeGrice in England, the appeals court did not specifically address any issue of such activity presumably because it occurred outside the United States.

4. The record of the appeal in <u>LeGrice</u> shows that the sale and/or public use of the two rose varieties was disposed by the Board.

There was no discussion about enablement of the printed publication based on public availability of the rose in the <u>LeGrice</u> decision reported by the CCPA because the issue of public availability of the roses outside the United States was disposed of in the lower {woo85319.1}

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decision at the Board of Appeals. See, <u>Application of Edward Burton LeGrice</u>, Decision of Board of Appeals, February 12, 1960 (attached hereto and hereinafter referred to as the "Board LeGrice Decision").

In the appeal to the Board by Mr. LeGrice, the Board correctly recognized that the "use or sale of the plants in a foreign country would be irrelevant" to the issue of novelty. <u>Id.</u> at page 25. Moreover, the Board found evidence of foreign sale and/or public use of the rose varieties.

The publications indicated that the particular plants were on sale, and presumably also in public use, more than one year prior to the respective filing dates of the applications since appellant is indicated as 'raiser and distributor.' However this question is not in issue since the public use or sale must be in the United States in order to bar a patent and these events, as far as anything suggested by the record is concerned, took place in England. The single broad issue of the competency of a prior printed publication to bar a plant patent is presented.

Id. at page 22.

Hence, the <u>LeGrice</u> court had plenty of evidence of commercial availability of the rose varieties outside the United States, and the stated presumption was that the plant was in public use. It did not directly address those facts since they were irrelevant to the novelty of the plant under United States statutory law and had been properly dispensed with by the Board of Appeals.

5. A publication is incapable of placing a plant variety in the public domain.

The <u>LeGrice</u> court focused on whether the publications (the Rose Annuals or the catalogs), when interpreted in light of the knowledge possessed by plant breeders, placed the rose varieties in the public domain. Importantly, when the court looked to what constituted the knowledge possessed by plant breeders, it did not even consider the evidence of prior use and/or sale of the rose varieties. The Board had dismissed any relevance of that evidence to the issue of novelty of the rose varieties in the United States.

Instead, the standard applied by the <u>LeGrice</u> court for the enablement of a publication under 35 U.S.C. § 102(b) is whether "a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention". <u>LeGrice</u> at 936, 133 USPQ at 372. The "knowledge" for a skilled artisan was not -- and still is not -- the commercial activity of the breeder outside the United States.

The "knowledge" of the skilled plant breeder includes plant genetics. In 1962, the knowledge of plant genetics meant that publications (such as the Rose Annuals and catalogs) could not be relied upon as statutory bars under 35 U.S.C. § 102(b). The <u>LeGrice</u> court cautioned, however, that each case must be decided on its own facts and that future studies may add to "the knowledge of plant breeders so that they may *someday* secure possession of a plant invention by a description in a printed publication". <u>Id.</u> at 939, n. 7, 133 USPQ at 374, n. 7.

There can be no dispute; that "someday" has not yet arrived.

6. The facts of <u>LeGrice</u>, non-enablement of a plant patent claim by a description of the plant, parallel the present case.

In both <u>LeGrice</u> and here, the material elements of a plant patent claim are not set forth in the printed publication and there is no need to consult additional references, nor is it appropriate to do so.

A PBR application which refers to a species of a plant, a plant name and a few bits of botanical data cannot be considered to be so "precise and particular" that a skilled artisan could "construct and operate it without experiments and without further exercise of inventive skill." The ability to purchase a begonia named 'Nadine' one year prior to the application filing date is not equivalent to the ability to "construct and operate" a new begonia variety named 'Nadine' based on the PBR application. One skilled in the art may have learned of a begonia named 'Nadine' – outside the United States. While public prior use and sale are avenues by which a plant enters the public domain, that prior use or sale must have occurred in the United States to rise to the level of a statutory bar. See 35 U.S.C. § 102(b).

A PBR application could lead one skilled in the art to find a plant to purchase outside the United States which bears a name mentioned in the PBR application. That scenario is not one which renders the PBR application enabling. It is simply a trail which leads to a sale of a plant outside the United States. There is no support in <u>LeGrice</u> or elsewhere for the proposition that sale of a named plant outside the United States automatically enables the publication of a PBR application listing a plant with the same name.

B. Ex parte Thomson

Naturally, a different result was found in <u>Ex parte Thomson</u> when the claims in a utility application for a cotton cultivar were rejected over a prior art reference which identically disclosed the specification of the application for the cotton cultivar. The rejected claims were as follows:

- 1. A cotton cultivar having the designation Siokra (ATTC 40405).
- 2. Seeds of the cotton cultivar according to Claim 1.

The Board of Patent Appeals and Interferences found that several prior art references disclosed the exact same cotton cultivar and seeds of that cultivar. Importantly, the Board found that "for enablement purposes, the descriptive words of the specification herein do not differ substantially from the disclosures of the cited publications". Id. at 1621 (emphasis added). Moreover, the specification of the utility application was enabled by the availability of the claimed seeds deposited in the American Type Culture Collection (ATTC). The cited publications were also enabled by the public availability of the same cotton seeds. Id. As such, the public accessibility of the claimed seeds would have enabled the skilled artisan to make and use the claimed cotton cultivar and its seeds. Id. The Board upheld the rejection of the claims under 35 U.S.C. § 102(b) based on (1) prior art references that identically disclosed the claimed cultivar and (2) the opportunity for a skilled cotton grower to read the prior art references, purchase the commercially available seeds, and employ conventional techniques to obtain the claimed invention, namely, the plants and its seeds.

The Board distinguished LeGrice for three reasons.

First, actually following <u>LeGrice</u>, it recognized that each case is decided upon its own facts in determining whether the description in a printed publication is "adequate to put the public in possession of the invention and bar patenting of a plant" under § 102(b). <u>Id.</u> at 1620. The Board believed that sufficient advancements in plant eugenics warranted not following <u>LeGrice</u>'s rule on non-enablement of publications and expressed no doubt that the skilled artisan would be able to grow the claimed cultivar. As detailed in Dr. Craig's Declaration, the Board was clearly mistaken. The "someday" of securing a plant invention by a description in a printed publication has not yet arrived. Regardless of the Board's erroneous comments on genetic technology, it remains axiomatic that each case must be decided on its own facts. <u>Id.</u>

Moreover, the <u>Thomson</u> Board clearly misunderstood the evidence of commercial availability of the rose varieties in <u>LeGrice</u> by stating that:

[LeGrice's] holding was based on the specific "printed publications" before it, and no indication was given that the "prior catalogue publication" before it evidenced commercial availability in a readily enabling form. The court simply stated that the prior catalog publication "includes a color picture of the rose clear enough to establish identity in appearance between the rose illustrated and applicants variety".

Thomson, 24 USPQ2d at 1621.

As detailed above, the <u>LeGrice</u> decision is replete with evidence of public use and/or sale of the rose varieties outside the United States. The irrelevance of those activities was disposed of by the Board.

Second, the Board found it significant that for enablement purposes the descriptive words of the specification did not differ substantially from the disclosures of the cited publications. <u>Id.</u> In other words, all the material elements of the claim were disclosed in the primary reference. The specification was enabled by the deposit of the claimed seeds and the cited publications were also enabled by the deposit of the same seeds. The court noted that <u>LeGrice</u> did not consider the public availability of the rose plant at issue therein, {woo85319.1}

and that the <u>LeGrice</u> holding was based on the specific printed publications. Public availability of the plant was one factor in the <u>Thomson</u> decision because the claim itself was enabled by public availability of the plant. However, a "significant" aspect of the 102(b) rejection was that the descriptive words of the prior art references did "not differ substantially" from the disclosures of the specification. <u>Id.</u>

Finally, the Board pointed out that whereas <u>LeGrice</u> was directed to patentability of plant patents, the patent at issue in <u>Thomson</u> was a utility patent which is afforded a broader scope of protection. <u>Id.</u> at note 1. Hence, the standard for anticipation by a printed publication is to be more broadly applied to the claims in a utility application than to a claim in a plant patent application. <u>Id.</u>

The Office Action in the present case incorrectly asserts that the same question was asked in <u>Thomson</u> and <u>LeGrice</u> of "what is required to enable" a printed publication describing a plant. The questions in those two cases must be different because <u>Thomson</u> involved a utility patent claim and <u>LeGrice</u> involved a plant patent claim -- and those are two different forms of statutory subject matter having different standards for enablement and infringement.

It should be understood that the <u>Thomson</u> decision is consistent with <u>Donohue</u> and <u>Samour</u> in meeting the requirements for using additional references in a § 102(b) rejection.

First, every material element of the <u>Thomson</u> claim was set forth in the primary reference. ("We find it significant for enablement purposes the descriptive words of the specification do not differ substantially from the disclosure of the cited publications"). <u>Thomson</u>, 24 USPQ2d at 1621.

Second, the additional "reference" (the publicly available seeds) was cited solely to show that the plant described fully in the primary reference was in the public domain. As was true for <u>Samour</u> and <u>Donohue</u>, the Thomson rejection did not combine teachings of two references. The added reference only demonstrated that the plant material fully described in the primary reference was in the public domain.

IV. Enablement of a PBR publication as a prior art reference is inconsistent with past and current examination practices in plant patent applications.

The standards for compliance with 37 C.F.R. § 1.163 and 35 U.S.C. § 112, first paragraph in plant patent applications have become increasingly strict. Despite the variance in the degree of description in a plant permitted by 35 U.S.C. § 162, recent experience shows that many disclosures of plant patent applications are objected to and the claims therein are rejected under 35 U.S.C. § 112 first and second paragraphs which require as follows (emphasis added):

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to **enable** any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The May 3, 2002 Office Action in the present application included an objection to the disclosure under the first paragraph of § 112 and a rejection of the claim under the first and second paragraphs of § 112 for asserted lack of "a full, clear, and complete botanical description of the plant and the characteristics which define same per se and which distinguish the plant from related known cultivars and antecedents".

Historically, the United States Patent and Trademark Office has not considered the information in a PBR application sufficient under §§ 112 and 162. More recently, even significantly more complete disclosures (such as the original specification filed herein) are not considered to be sufficiently complete (not enabling) under the statute.

To now assert that a PBR application somehow is enabling prior art (alone or in combination with sale or use outside the United States) is inconsistent with the examination practice of requiring detailed botanical information in plant patent applications. The United States Patent and Trademark Office cannot have it both ways of asserting a PBR

application as enabling prior art and rejecting reasonably detailed plant patent applications for lack of enablement. Moreover, this new interpretation of PBR applications as being enabling prior art is contrary to decades of plant patent examination policy and practice.

Future plant patent applicants can comply with the stricter interpretation of § 162 when submitting their applications, but they should not be faced with a prior art rejection based on a non-enabling PBR document.

IX

THE REALITIES OF PLANT BREEDING

Time delays in breeding new plant varieties exist whether the breeding occurs in the United States or elsewhere. In the case of plants bred outside the United States, additional testing and trialing in the United States must take place to make sure the new plants are adaptable to the climatic conditions in this country. This often takes several years before the plants are deemed acceptable and actually enter the United States market. Only a few varieties tested and trialed in the United States actually enter the United States market, and it is not economically feasible to file immediately on every variety to be tested. The new patent policy requires that such immediate filing take place thereby placing the foreign plant patent breeder at a distinct economic disadvantage.

A plant bred in The Netherlands can be introduced much more quickly in The Netherlands because it was bred and grown there from the outset. Therefore, there is often a sale in Europe more than one year before the United States plant patent application is filed. A sale outside the United States does not trigger a statutory patent bar and does not diminish the need to afford protection to foreign plant breeders seeking to introduce their horticultural developments into the United States.

This concept has been understood since at least the time that the Townsend-Purnell Plant Patent Act become law in 1930. The Plant Patent Act of 1930 was enacted "to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry." H.R 1129, 71st Congress, 2d Session (1930).

Today the plant breeder has no adequate financial incentive to enter upon his work. A new variety once it has left the hands of the breeder may be reproduced in unlimited quantity by all. The originator's only hope of financial reimbursement is through high prices for the comparatively few reproductions that he may dispose of during the first two or three years. After that time, depending on the speed with which the plant may be asexually reproduced, the breeder loses all control of his discovery. Under the bill the originator will have control of his discovery during a period of 17 years, the same term as under industrial patents. If the new variety is successful, the breeder or discoverer can expect an adequate financial reward.

Id.

Under the current examination practice, rejection of plant patent applications by foreign breeders who have not yet introduced their discoveries into the United States cuts off their opportunities of reaping adequate financial reward in the United States. Plant varieties which are not ready for introduction into the United States, but were sufficiently developed in Europe to be introduced there, are not given the benefit of the patent system as was intended by the Plant Patent Act of 1930. Without that benefit, foreign plant breeders "only hope of financial reimbursement is through high prices for the comparatively few reproductions that [they] may dispose of during the first two or three years" following introduction of varieties into the United States. Id. The Plant Patent Act of 1930 was adopted so that "plant patents will mean better agricultural products that will give the public more actual value for its dollar". Due to the current rejection policy and to the detriment of the public, advances in agriculture made outside the United States may not reach this country.

This policy by the United States Patent and Trademark Office represents a radical departure from any previous policy in the area of plant patent law. It has been estimated that under such a radical policy, 70% of the extant plant patents issued to foreign applicants in the United States are invalid.

Relying on use and sales outside the United States to turn a non-enabling plant disclosure into an enabling one was never contemplated by drafters of the Plant Patent Act, is

not recognized by statute, is contrary to Patent Office policy from at least as early as the <u>LeGrice</u> decision (1962) and makes absolutely no sense to anyone skilled in the art. This new radical policy needs to be promptly reversed so foreign plant breeders again have opportunities in this country to file United States plant patent applications.

X CONCLUSION

In the absence of disclosure of every material element of the claimed subject matter, the PBR document fails to meet the anticipation requirements of 35 U.S.C. § 102(b). The sale of the claimed variety outside the United States more than one year prior to the filing date of the United States patent application can be relied upon only to show that the claimed subject matter was in the possession of the public and not to supplement the impossibility of a PBR application to disclose every material element of the claimed invention.

The plant patent examining group has created a new position on prior art to plant patent applications that is counter to decades of examination. This policy, if not withdrawn, will have the effect of essentially blocking United States plant patents on plant varieties discovered in foreign countries. It represents the ultimate disservice to the foreign breeder.

This new position has no basis in fact or in law and is based in part on a false premise, namely, that <u>LeGrice</u> did not deal with sale in a foreign country. According to statute, the sale puts the variety in a certain public domain, but not the public domain which constitutes a statutory bar - it is not "in this country" as required by 35 U.S.C. § 102(b). Moreover, the "someday" of plant genetics from <u>LeGrice</u> has not arrived. A printed publication cannot bar patenting of a plant because a plant variety cannot be created from a description of the plant.

The only § 102(b) bar to plant patent applications is the sale, offer for sale, or public use of the plant itself within the United States. Likewise, the invention of a plant patent is the plant itself. A plant patent can have but one claim -- to the plant itself. Plant

patent infringement requires proof that the infringing plant is an asexually reproduced progeny of the parent plant -- it requires access to the plant itself. <u>Imazio Nursery, Inc. v. Dania Greenhouses</u>, 69 F.3d 1560, 36 USPQ2d 1673 (Fed. Cir. 1995).

It follows that the plant itself must be present in the United States to bar novelty under §102(b). The asserted enablement of a printed publication by "non-prior art" (sale outside the United States) is an attempt to thwart the statutory requirement that the plant itself be present in the United States to bar a plant patent in light of today's understanding of plant genetics. The anticipation rejection should be withdrawn.

A check in the amount of \$330.00 accompanies this Appeal Brief. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees which may be required to Deposit Account No. 23-0650. Please refund any overpayments to Deposit Account No. 23-0650. An original and two copies of this Appeal Brief are enclosed.

Respectfully submitted,

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APPENDIX A

I Claim:

1. A new and distinct variety of begonia plant substantially as shown and described.